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Dohmen, Pascal M; Markou, Thanasie; Ingemansson, Richard; Rotering, Heinrich; Hartman, Jean M; van Valen, René; Brunott, Maaïke; Kramer, Axel; Segers, Patrique

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LUND UNIVERSITY

PO Box 117  
221 00 Lund  
+46 46-222 00 00

# Can post-sternotomy mediastinitis be prevented by a closed incision management system?

## Kann Mediastinitis bei Zustand nach Sternotomie durch einen Vakuumverband verhindert werden?

### Abstract

Post-sternotomy mediastinitis is a serious complication after cardiothoracic surgery and contribute significantly to post-operative morbidity, mortality, and healthcare costs. Negative pressure wound therapy is today's golden standard for post-sternotomy mediastinitis treatment. A systematic literature search was conducted at PubMed until October 2012 to analyse whether vacuum-assisted closure technique prevents mediastinitis after clean surgical incisions closure. Today's studies showed reduction of post-sternotomy mediastinitis including a beneficial socio-economic impact. Current studies, however included only high-risk patients, hence furthermore, larger randomised controlled trials are warranted to clarify the benefit for using surgical incision vacuum management systems in the general patient population undergoing sternotomy and clarify risk factor interaction.

**Keywords:** incisional negative pressure therapy, cardiothoracic surgery, surgical wounds, surgical site infection, closed incision management, negative pressure wound therapy (NPWT)

### Zusammenfassung

Mediastinitis bei Zustand nach Sternotomie ist eine ernste Komplikation nach herz- und thoraxchirurgischen Eingriffen, die durch eine Vielzahl von Faktoren beeinflusst wird. Sie ist mit erhöhter Morbidität, Mortalität und behandlungsassoziierten Kosten verbunden.

Die Vakuumtherapie ist der heutige Standard zur Mediastinitisbehandlung bei Zustand nach Sternotomie. Im vorliegenden Minireview wird analysiert, ob der Vakuumverband auch in die Lage ist, einer Mediastinitis vorzubeugen.

Im Ergebnis einer systematischen Literaturrecherche in PubMed wurde festgestellt, dass die Anwendung des Vakuum-assoziierten Verschlusses eine Reduktion der Mediastinitis zur Folge hatte. Ebenso konnten die behandlungsassoziierten Kosten gesenkt werden. Allerdings waren in allen Studien nur Hoch-Risiko-Patienten eingeschlossen, sodass dringend weiterte Studien zur Absicherung der Ergebnisse einschließlich der Abklärung von Risikofaktoren benötigt werden.

Pascal M. Dohmen<sup>1</sup>  
Thanasie Markou<sup>2</sup>  
Richard Ingemansson<sup>3</sup>  
Heinrich Rotering<sup>4</sup>  
Jean M. Hartman<sup>5</sup>  
René van Valen<sup>6</sup>  
Maaïke Brunott<sup>6</sup>  
Axel Kramer<sup>7</sup>  
Patrique Segers<sup>8</sup>

1 Department of Cardiac Surgery, Heart Center Leipzig, University of Leipzig, Germany

2 Department of Cardiothoracic Surgery, Isala Klinieken Zwolle, The Netherlands

3 Department of Cardiothoracic Surgery, University Hospital of Lund, Sweden

4 Department of Cardiothoracic Surgery, University Clinic Münster, Germany

5 Department of Cardiothoracic Surgery, University Medical Center Groningen, The Netherlands

6 Department of Cardiothoracic Surgery, Erasmus University Rotterdam, The Netherlands

7 Institute of Hygiene and Environmental Medicine, University Medicine Greifswald, Germany

8 Department of Cardiothoracic Surgery, Academic Medical Center Amsterdam, The Netherlands

## Introduction

Post-sternotomy mediastinitis is a serious complication after cardiothoracic surgery and contribute significantly to post-operative morbidity, mortality, and healthcare costs [1]. Negative pressure wound therapy is today's golden standard for post-sternotomy mediastinitis treatment due to oedema reduction, removing exudation, increase wound perfusion, stimulate granulation formation, and decrease microbial colonization [1]. This positive effect on wound healing triggered the interest in using negative pressure wound therapy after closure of clean surgical incisions in contrast with traditional wound care such as gauze dressings, hydrocolloids, growth factors or cultured skin to prevent surgical site infections, especially post-sternotomy mediastinitis. The surgical incision management system (Prevena™ Incision Management System, Kinetic Concepts, Inc. USA, San Antonio, TX, USA) is a single-use, battery-powered therapy unit that delivers negative pressure of  $-125$  mmHg [2]. Surgical incision management holds the incision edges together, reduces lateral tension and oedema, stimulates perfusion, and protects the surgical site from external infectious sources [3]. The skin interface layer containing 0.019% ionic silver, allows no direct contact of the foam, wicks fluid from the skin surface, and reduces bacterial colonisation within the fabric.

High-quality, multi-centre or single-centre, randomised controlled trials (level I based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons) [4] in other clean surgery fields [5] showed positive outcomes by using incisional negative pressure wound therapy. These results encourage using surgical incision management, which is functionally equivalent to incisional negative pressure wound therapy, in high-risk patients undergoing median sternotomy to prevent post-sternotomy mediastinitis. Therefore a systematic of the literature was performed.

## Method

The systematic literature search at PubMed was conducted through October 30<sup>th</sup> 2012. The following key words were included: "negative pressure wound therapy" and "sternotomy wound infection prevention" and "cardiac surgery". Excluded were case reports and articles not preventing surgical site infections but treated.

## Results

The largest prospective comparative study (Level II) was performed by Grauhan et al. [6] including 150 consecutive obese (body mass index  $>30$  kg/m<sup>2</sup>) patients with median sternotomy. Standard wound dressings were applied in the control group ( $n=75$ ), while the treatment group received surgical incision management ( $n=75$ ). This study showed significant reduction of surgical site infections

(SSI) after median sternotomy, respectively 16% versus 4% (OR 4.57, CI 95% 1.23–16.94;  $p=0.0266$ ).

Atkins et al. [7] examined 57 adult cardiac surgery patients at higher risk for sternal wound infection, who were treated with incisional negative pressure wound therapy (Level III). Patient population included morbid obesity (77.2%), diabetics (54.4%), and obese plus diabetic (50.9%). Overall, 50.9% of patients underwent coronary artery bypass graft with one internal mammary artery and 14% with bilateral mammary artery use. Approximately 20% underwent coronary artery bypass graft with concomitant procedures. Since this study included no control group the estimated risk for post-sternotomy mediastinitis was based on risk scores, which predict SSI. Based on this system, the estimated average risk for developing post-operative post-sternotomy mediastinitis in this group of high-risk cardiac surgery patients was  $6.1 \pm 4.0\%$ ; therefore, at least three cases of post-sternotomy mediastinitis were expected in this study population. Ten patients (17.5%) required readmission within the first 30 days after discharge; however, no admissions were due to sternal wound complications. Therefore the authors recommend that incision negative pressure wound therapy should be strongly considered for patients with increased risk of surgical site infection.

Finally Colli et al. [8] used surgical incision management over the surgical incisions of a small case series of ten patients at high risk for post-sternotomy mediastinitis following coronary artery bypass graft surgery (Level III). Surgical incision management was used for 5 continuous days immediately following sternal wound closure. This study also included no control group, and therefore the authors again utilised a risk score system finding a prediction of  $6.4 \pm 4.4\%$  for post-sternotomy mediastinitis. This high-risk cardiac surgery population included, diabetes in all, peripheral vessel disease in 90%, morbid obesity in 50%, chronic obstructive pulmonary disease in 30%, and renal failure in 20%. The left internal mammary artery was used in 100% and bilateral mammary artery grafting was performed in 50%. The system was well tolerated and all patients experienced complete wound healing with no evidence of early or late wound infections. The authors again recommend the use of surgical incision management in high-risk cardiac patients. These preliminary findings demonstrate the favourable efficacy and safety of surgical incision management systems in preventing wound complications after cardiac surgery in high-risk patients.

## Discussion

The remarkable infection-preventive effect raises the question of the possible causes. The bacterial density in wounds predicts the risk of wound infection with subsequent healing [9], [10], [11]. Therefore, it was obvious that negative pressure affects the bacterial colonization. But some studies on acute and chronic wounds refutes that bacterial bioburden is consistently lessened during

VAC therapy [12], [13]. In an in vitro wound model bacterial load of sponges with or without negative pressure did not differ [14]. The reduction in bacteria demonstrated in previous studies appears to be caused by other effects than physical suction alone. Since primary closed sternotomy wounds are not critically colonized, other mechanisms must be responsible. From a theoretical considerations point of view, following factors could affect a favourable outcome: (i) improved circulation and increased of vascularity [15], (ii) stimulation of cell proliferation [15], (iii) immediate tight aseptic wound closure, (iv) microbio-static activity of polyurethane-coated polyester fabric with silver and (v) optimal wound edges adaptation. Using a computer model, the hypothesis was generated, that micromechanical forces may be stimulate wound healing through promotion of cell division, angiogenesis, and local elaboration of growth factors [16]. These questions should be analyzed in further studies i.e. in sensitive animal models.

## Conclusion

All studies showed reduction of expected post-sternotomy mediastinitis in high-risk cardiac surgery patients for SSI such as morbid obesity, including obesitas per magna, insulin-dependent diabetes, chronic renal failure, and bilateral mammary artery grafting. Other risk-factors including low body mass index ( $<18 \text{ kg/m}^2$ ), long-term immunosuppressive therapy, high age and female gender, need to be investigated. Furthermore, larger randomised controlled trials are warranted to clarify exact benefit for the use of a surgical incision management system. These studies should not only include reduction of surgical site infection, including patient's morbidity and mortality, but also investigate the social economic impact. Due to the complexity of SSI and multiple factors influencing post-sternotomy mediastinitis, additional studies are needed to improve wound healing in cardiac surgery patients bringing prevention measures in proportion to risk factors.

## Notes

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## Conflict of interest

All authors declare that they have no conflicts of interest.

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**Corresponding author:**

Prof. Dr. Pascal M. Dohmen  
Department of Cardiovascular Surgery, Charité Hospital,  
Medical University Berlin, Chariteplatz 1, 10117 Berlin,  
Germany, Phone: +49 30 450 522092, Fax: +49 30 450  
522921  
[pascal.dohmen@yahoo.de](mailto:pascal.dohmen@yahoo.de)